# UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF IOWA WESTERN DIVISION

JILL FENDER,
as Special Administrator and Surviving
Parent of the ESTATE OF MELISSA A.
FENDER, Deceased

Civil Action No.

Plaintiff,

v.

BAYER CORPORATION, an Indiana corporation clo CSC-Lawyers Incorporating Service (Corporation Service Company) 50 W. Broad St. Suite 1800 Columbus, OH 43215 COMPLAINT AND JURY DEMAND

BAYER HEALTHCARE
PHARMACEUTICALS INC.,
a Delaware corporation
clo CSC-Lawyers Incorporating
Service (Corporation Service Company)
50 W. Broad St. Suite 1800
Columbus, OH 43215

BAYER HEALTHCARE, LLC, a Delaware corporation clo CSC-Lawyers Incorporating Service (Corporation Service Company) 50 W. Broad St. Suite 1800 Columbus, OH 43215

BERLEX LABORATORIES
INTERNATIONAL, INC.,
a Delaware corporation
clo CSC-Lawyers Incorporating
Service (Corporation Service Company)
50 W. Broad St. Suite 1800
Columbus, OH 43215,

Defendants.

#### **COMPLAINT**

Plaintiff, Jill Fender appointed as Special Administrator of the Estate of Melissa A. Fender, deceased, Mills County Iowa, by and through counsel, and for her Complaint against Defendants, alleges as follows:

## PARTIES AND JURISDICTION

- 1. This is an action brought by Jill Fender, Special Administrator of the Estate of Decedent, Melissa Fender, pursuant to Letters of Appointment issued July 16, 2009 by the Iowa District Court, Mills County, Iowa, Case No. ESPR010463.
  - 2. Decedent Melissa Fender was the daughter of Jill and Martin Fender.
- 3. Decedent Melissa A. Fender was prescribed in or about November, 2006 and purchased and ingested Yaz until the time of her death. Melissa was prescribed and purchased Yaz in Pottawattamie County, Iowa. On or about July 27, 2007, while using Yaz, Melissa suffered pulmonary emboli resulting in her death.
- 4. At the time of her death, Melissa A. Fender was a resident and citizen of Sherburn, Minnesota, located in Martin County.
- 5. Plaintiff Jill Fender is a resident and citizen of Glenwood, Iowa, located in Mills County.
- 6. Plaintiff alleges an amount in controversy in excess of Seventy-Five Thousand Dollars (\$75,000.00), exclusive of interest and costs.
- 7. Defendant Bayer Corporation is an Indiana corporation with its principal place of business at 100 Bayer Road, Pittsburgh, Pennsylvania 15205. At relevant times, Defendant Bayer Corporation was engaged in the business of researching, developing,

designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drug Yaz. At relevant times, Defendant Bayer Corporation conducted regular and sustained business in Iowa by selling and distributing its products in Iowa and engaged in substantial commerce and business activity in Mills and Pottawattamie Counties.

- 8. Defendant Bayer Healthcare Pharmaceuticals, Inc. is a Delaware corporation, with its principal place of business at 6 West Belt Road, Wayne, New Jersey, 07470. Bayer Healthcare Pharmaceuticals, Inc. was created by the integration of Bayer Healthcare and Berlex Laboratories. Defendant Bayer Healthcare Pharmaceuticals, Inc. is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drug Yaz. At relevant times, Defendant Bayer Healthcare Pharmaceuticals, Inc. conducted regular and sustained business in Iowa by selling and distributing its products in Iowa and engaged in substantial commerce and business activity in Mills and Pottawattamie Counties.
- 9. Defendant Bayer Healthcare, LLC is a Delaware limited liability company, with its principal place of business at 555 White Plains Road, Tarrytown, New York, 10591. Bayer Healthcare, LLC was involved in the integration of Bayer Healthcare and Berlex Laboratories. Defendant Bayer Healthcare, LLC is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly

through third parties or related entities, its products, including the prescription drug Yaz. At relevant times, Defendant Bayer Healthcare, LLC conducted regular and sustained business in Iowa by selling and distributing its products in Iowa and engaged in substantial commerce and business activity in Mills and Pottawattamie Counties.

- 10. Defendant Berlex Laboratories International, Inc. was a Delaware corporation with its principal place of business in Montville, New Jersey. Berlex Laboratories International, Inc. was integrated with Bayer Healthcare, leading to the creation of Bayer Healthcare Pharmaceuticals, Inc. Defendant Berlex Laboratories International, Inc. was engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drug Yaz. At all relevant times, Defendant Berlex Laboratories International, Inc. conducted regular and sustained business in Iowa by selling and distributing its products in Iowa and engaged in substantial commerce and business activity in Mills and Pottawattamie Counties.
- 11. Defendants Bayer Corporation, Bayer Healthcare Pharmaceuticals, Inc., Bayer Healthcare, LLC, and Berlex Laboratories International, Inc. are collectively referred to herein as "Bayer" or "Defendants."
- 12. This court has jurisdiction over this action pursuant to 28 U.S.C. §1332 because there is complete diversity of citizenship between the parties, and the amount in controversy exceeds \$75,000.00, exclusive of interest and costs.
- 13. Venue in this district is appropriate under 28 U.S.C. §1391 because a substantial part of the events giving rise to this claim occurred in the district as

Defendants marketed, distributed, sold and/or introduced into interstate commerce the product, Yaz in this district and because Decedent Melissa A. Fender was prescribed, used, and purchased Yaz in this district.

#### FACTUAL BACKGROUND

## **Nature of the Case**

14. Plaintiff brings this case against Defendants for damages associated with Decedent Melissa Fender's ingestion of the pharmaceutical drug Yaz (ethinyl estradiol and drospirenone), an oral contraceptive designed, manufactured, marketed, and distributed by Defendants. Specifically, as a direct result of her use of Yaz, Deceased suffered multiple bilateral pulmonary emboli resulting in her death on July 27, 2007. Decedent's mother, Jill Fender, has suffered a loss of consortium.

## Bayer's Combined Oral Contraceptives - Yaz and Yasmin

- 15. Yaz and Yasmin are birth control pills manufactured and marketed by Defendants. They are combination oral contraceptives, or "COCs," meaning that they contain an estrogen component and a progestin component. Together, these steroidal components work together in COCs to suppress ovulation, fertilization, and implantation and thus prevent pregnancy.
- 16. Yaz and Yasmin were approved by the Food and Drug Administration for marketing in 2006 and 2001, respectively.

# Yaz and Yasmin contain a "Fourth Generation" Progestin.

17. The estrogen component in Yaz and Yasmin is known generically as ethinyl estradiol. The progestin component is known as drospirenone. Yasmin contains

0.03 milligrams of ethinyl estradiol, and Yaz contains 0.02 milligrams of ethinyl estradiol. Both products contain 3 milligrams of drospirenone.

- 18. Yaz and Yasmin are different from other combined hormonal birth control pills in that they contain drospirenone, a progestin that is unlike other progestins available in the United States and was never before marketed in the United States prior to its use in Yasmin.
- 19. Shortly after the introduction of combined oral contraceptives in the 1960's, doctors and researchers found that women using birth control pills had a higher risk of blood clots, heart attacks, and strokes than women not using the pill. As a result, the various brands of birth control pills were reformulated to reduce the amounts of estrogen. As the amounts of estrogen levels reduced, so too did the risk of blood clots, heart attacks, and strokes.
- 20. During this time, new progestins were being developed, which became known as "second generation" progestins (e.g. lovenorgestrel). These second generation progestins, when combined with the lower amounts of the estrogen, ethinyl estradiol, helped to reduce the risk of blood clots, heart attacks, and strokes and were considered safer for women.
- 21. During the 1990's, new "third generation" progestins were developed. Unfortunately, these "third generation" progestins (e.g. gestodene and desogestrel) have been associated with a greater risk of blood clots in the deep veins (deep vein thrombosis or "DVT") and lungs (pulmonary embolism or "PE"). As a result of this increased risk of blood clots, the FDA has required that products containing third generation progestins include a Warning of the potentially increased risk of thrombosis.

- 22. Yaz and Yasmin contain the same estrogen component, ethinyl estradiol, that has been used in the lower dose birth control pills for decades.
- 23. However, drospirenone is a new type of progestin and is considered a "fourth generation" progestin. No other birth control pills contain drospirenone, except for a recently approved generic version of Yaz and Yasmin marketed under the trade name Ocella.
- 24. Since drospirenone is new, there is insufficient data available to support its safe use, particularly compared with second generation progestins. In fact, studies performed prior to FDA approval indicate that drospirenone has certain effects that are different from those of traditional second generation progestins, and potentially more dangerous.
- 25. One possible mechanism of action is that drospirenone causes an increase in potassium levels in the blood, which can lead to a condition known as hyperkalemia if the potassium levels become too high. Hyperkalemia can cause heart rhythm disturbances, such as extrasystolies, pauses, or bradycardia. If left untreated, hyperkalemia can be fatal. If hyperkalemia disrupts the normal heart rhythms, the flow of blood through the heart can be slowed to the point that it permits blood clots to form. Blood clots in the heart can then lead to heart attacks, or the clots can break off and travel to the lungs where they can cause pulmonary embolism, or can travel to the brain causing stroke.
- 26. During the brief time that Yaz and Yasmin have been sold in the United States, hundreds of reports of injury and death have been submitted to the FDA in association with Defendants' products.

- 27. In April 2002, the British Medical Journal reported that the Dutch College of General Practitioners recommended that older second generation birth control pills be prescribed in lieu of Yasmin as a result of 40 cases of venous thrombosis among women taking Yasmin.
- 28. In February 2003, a paper entitled *Thromboembolism Associated With the New Contraceptive Yasmin* was published in the British Medical Journal detailing a Netherlands Pharmacovigilance Centre report of five additional reports of thromboembolism where Yasmin was suspected as the cause, including two deaths.
- 29. In fact, in less than a five-year period, from the first quarter of 2004 through the third quarter of 2008, over 50 reports of death among users of Yaz and Yasmin have been filed with the FDA.
- 30. These reports include deaths associated with cardiac arrhythmia, cardiac arrest, intracardiac thrombus, pulmonary embolism, and stroke in women in their child bearing years.
  - 31. Some deaths reported occurred in women as young as 17 years old.
- 32. Significantly, reports of elevated potassium levels are frequently included among the symptoms of those suffering death while using Yasmin or Yaz.

#### Over-Promotion of Yasmin and Yaz

- 33. Defendants market Yaz and Yasmin as providing the same efficacy as other birth control pills in preventing pregnancy, but with additional benefits.
- 34. However, because Yaz and Yasmin contain the fourth generation progestin drospirenone, they present additional health risks not associated with other birth control pills.

- 35. For example, prior to its sale to Defendant Bayer in 2006, Defendant Berlex Laboratories promoted Yasmin's fourth generation progestin, drospirenone, by stating, "Ask about Yasmin, and the difference a little chemistry can make."
- 36. In response, on July 10, 2003, the FDA objected to the characterization that drospirenone was a benefit compared to the progestin used in other combined oral contraceptives, and issued a warning letter stating, "FDA is not aware of substantial evidence of substantial clinical experience demonstrating that Yasmin is superior to other COCs or that the drospirenone in Yasmin is clinically beneficial. On the contrary, FDA is aware of the added clinical risks associated with drospirenone [.]"
- 37. The FDA's warning letter continued by stating that the advertisement failed "to communicate that the potential to increase potassium is a risk" or that "increased serum potassium can be dangerous."
- 38. More recently, Defendants advertised that its product Yaz was indicated for treatment of premenstrual syndrome or "PMS," as opposed to the less serious condition of premenstrual dysphoric disorder or "PMDD."
- 39. Defendants also advertised that Yaz contained the added benefit of preventing or reducing acne.
- 40. In response, on October 3, 2008, the FDA issued another warning letter to Defendant Bayer for the misleading advertisement, reiterating that the marketing was misleading because it promoted Yaz for medical conditions beyond the limits of the FDA approval, and adding that "Yaz has additional risks because it contains the progestin, drospirenone ... which can lead to hyperkalemia in high risk patients, which may result in potentially serious heart and health problems."

- 41. The FDA further warned in its October 3, 2008 letter that Yaz "does not result in completely clear skin" and that Defendants' "TV Ads misleadingly overstate the efficacy of the drug."
- 42. Indeed, the FDA felt Defendants' over-promotion was so severe that it required Bayer to run new TV advertisements to correct the previous misleading Yaz advertisements regarding acne and premenstrual syndrome.
- 43. Bayer ultimately agreed to spend at least \$20 million on corrective TV advertisements and to submit all Yaz advertisements to the FDA for advanced screening for the next six years.

## Decedent's Use of Yaz and Resulting Injuries

- 44. As a result of Defendants' claims regarding the effectiveness and safety of Yaz, Decedent Melissa A. Fender's medical provider prescribed and Melissa began using Yaz in or about November, 2006. Decedent used Yaz until July 27, 2007, the date she suffered pulmonary emboli, resulting in her death.
- 45. As a direct and proximate result of using Yaz, Melissa A. Fender suffered the injuries described above.
- 46. Prior to Decedent's use of Yaz, Defendants knew or should have known that use of Yaz created a higher risk of pulmonary embolism than other oral contraceptives on the market, including but not limited to second generation oral contraceptives, and that, when taken as directed, such use was unreasonably dangerous to consumers.
- 47. Therefore, at the time Melissa A. Fender used Yaz, Defendants knew or should have known that the use of Yaz created an increased risk to consumers of serious

personal injury, including deep vein thrombosis, pulmonary embolism, heart attacks, stroke, and even death.

- 48. Despite the fact that Defendants knew or should have known of the serious health risks associated with the use of Yaz, Defendants failed to warn Melissa A. Fender and/or her health care providers of said serious risks before she used the product.
- 49. Had Melissa A. Fender and/or her heath care providers known the risks and dangers associated with Yaz, she would not have used Yaz and would not have suffered pulmonary emboli, resulting in her death on July 27, 2007.
- 50. As a direct and proximate result of her use of Yaz, Decedent suffered physical injury, including but not limited to, conscious pain and suffering, as a result of her pulmonary emboli.
- 51. As a direct and proximate result of Decedent's use of Yaz, Plaintiff has suffered and will continue to suffer pecuniary losses.
- 52. As a direct and proximate result of Decedent Melissa A. Fender's use of Yaz and resulting injuries, her mother, Plaintiff Jill Fender, has suffered damages and harm, including but not limited to, emotional distress and has incurred other medical expenses and other economic harm, as well as loss of consortium, services, society, companionship, love and comfort.

#### FIRST CAUSE OF ACTION

# **Strict Products Liability Defective Manufacturing**

53. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows.

- 54. Defendants are the manufacturers, designers, distributors, sellers, or suppliers of Yaz.
- 55. The Yaz birth control pills manufactured, designed, sold, distributed, supplied and/or placed in the stream of commerce by Defendants were expected to and did reach the consumer without any alterations or changes.
- 56. The Yaz birth control pills manufactured, designed, sold, distributed, supplied and/or placed in the stream of commerce by Defendants, were defective in their manufacture and construction when they left the hands of Defendants in that they deviated from product specification such that they were unreasonably dangerous to an ordinary user or consumer and posed a serious risk of injury and death.
- 57. As a direct and proximate result of Decedent's use of Yaz as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, Decedent suffered personal injuries and death, and Decedent and Plaintiff suffered economic and non-economic damages. Furthermore, Plaintiff suffered the loss of daughter, Melissa Fender.
- 58. As a direct and proximate result of Decedent Melissa A. Fender's use of Yaz and resulting injuries, her mother, Jill Fender, has suffered damages and harm, including but not limited to, emotional distress and has incurred other medical expenses, funerary expenses, and other economic harm, as well as loss of consortium, services, society, companionship, love and comfort, and will continue to suffer such harm in the future.
- 59. Defendants' actions and omissions as identified in this Complaint show that Defendants acted maliciously, with aggravated or egregious fraud, and/or intentionally disregarded Decedent's rights, so as to warrant the imposition of punitive damages.

## SECOND CAUSE OF ACTION

# Strict Products Liability Design Defect

- 60. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows.
- 61. Defendants are the manufacturers, designers, distributors, sellers, or suppliers of Yaz.
- 62. The Yaz birth control pills manufactured, designed, sold, distributed, supplied and/or placed in the stream of commerce by Defendants were expected to and did reach the consumer without any alterations or changes.
- 63. The Yaz birth control pills manufactured and supplied by Defendants were defective in design or formulation in that, when it left the hands of the Defendants, the foreseeable risks of the product exceeded the benefits associated with its design or formulation, or they were more dangerous than an ordinary consumer would expect.
- 64. The foreseeable risks associated with the design or formulation of the Yaz birth control pills, include, but are not limited to, the fact that the design or formulation of Yaz is more dangerous than a reasonably prudent consumer would expect when used in an intended or reasonably foreseeable manner.
- 65. As a direct and proximate result of Decedent's use of Yaz as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, Decedent Melissa A. Fender suffered personal injuries, death, economic and non-economic damages, including pain and suffering.
- 66. As a direct and proximate result of Decedent Melissa A. Fender's use of Yaz and resulting injuries, her mother, Plaintiff Jill Fender, has suffered damages and harm,

including but not limited to, emotional distress and has incurred other medical expenses and other economic harm, as well as loss of consortium, services, society, companionship, love and comfort, and will continue to suffer such harm in the future.

67. Defendants' actions and omissions as identified in this Complaint show that Defendants acted maliciously, with aggravated or egregious fraud, and/or intentionally disregarded Decedent's rights, so as to warrant the imposition of punitive damages.

### THIRD CAUSE OF ACTION

# Strict Products Liability Defect Due to Inadequate Warning

- 68. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows.
- 69. The Yaz birth control pills manufactured and supplied by Defendants were defective due to inadequate warning or instruction and was unreasonably dangerous to the ordinary user or consumer because Defendants knew or should have known that the product created significant risks of serious bodily harm and death to consumers and they failed to adequately warn consumers and/or their health care providers of such risks.
- 70. The Yaz birth control pills manufactured and supplied by Defendants were defective due to inadequate post-marketing warning or instruction and were unreasonably dangerous to the ordinary user or consumer because, after Defendants knew or should have known of the risk of serious bodily harm and death from the use of Yaz, Defendants failed to provide an adequate warning to consumers and/or their health care providers of the product, knowing the product could cause serious injury and death.

- 71. As a direct and proximate result of Decedent's use of Yaz as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, Decedent suffered personal injuries, death, economic and non-economic damages.
- 72. As a direct and proximate result of Decedent Melissa A. Fender' use of Yaz and resulting injuries, her mother, Plaintiff Jill Fender, has suffered damages and harm, including but not limited to, emotional distress and has incurred other medical expenses and other economic harm, as well as loss of consortium, services, society, companionship, love and comfort, and will continue to suffer such harm in the future.
- 73. Defendants' actions and omissions as identified in this Complaint show that Defendants acted maliciously, with aggravated or egregious fraud, and/or intentionally disregarded Decedent's rights, so as to warrant the imposition of punitive damages.

#### FOURTH CAUSE OF ACTION

### Negligence

- 74. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows.
- 75. Defendants had a duty to exercise reasonable care in the design, manufacture, sale and/or distribution of Yaz into the stream of commerce, including a duty to assure that its product did not pose a significantly increased risk of bodily harm and adverse events.
- 76. Defendants failed to exercise ordinary care in the design, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, promotions and distribution of Yaz into interstate commerce in that Defendants knew or

should have known that the product caused such significant bodily harm or death and was not safe for use by consumers.

- 77. Defendants also failed to exercise ordinary care in the labeling of Yaz and failed to issue to consumers and/or their health care providers adequate warnings of the risk of serious bodily injury or death due to the use of Yaz.
- 78. Despite the fact that Defendants knew or should have known that Yaz posed a serious risk of bodily harm to consumers, Defendants continued to manufacture and market Yaz for use by consumers.
- 79. Defendants knew or should have known that consumers, including Melissa A. Fender, would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above.
- 80. As a direct and proximate result of Defendants' negligence, Decedent suffered personal injuries, death, economic and non-economic damages.
- 81. As a direct and proximate result of Melissa A. Fender's use of Yaz and resulting injuries, her mother, Plaintiff Jill Fender, has suffered damages and harm, including but not limited to, emotional distress and has incurred other medical expenses and other economic harm, as well as loss of consortium, services, society, companionship, love and comfort, and will continue to suffer such harm in the future.
- 82. Defendants' conduct as described above, including but not limited to its failure to adequately test Yaz, to provide adequate warnings, and its continued manufacture, sale and marketing of the product when it knew or should have known of the serious health risks it created, evidences malicious actions, aggravated or egregious fraud, and/or

intentional disregard of the rights of Decedent, so as to warrant the imposition of punitive damages.

## FIFTH CAUSE OF ACTION

# Negligent Misrepresentation and/or Fraud

- 83. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:
- 84. Defendants are the manufacturers, designers, distributors, sellers or suppliers of Yaz and made representations to Defendant and her healthcare providers regarding the character or quality of Yaz for guidance in their decision to select Yaz.
- 85. Specifically, Defendants represented that their product was just as safe or safer, and just as effective or more effective, than other birth control products on the market.
- 86. Defendants' representations regarding the character or quality of Yaz were untrue.
- 87. Defendants had actual knowledge based upon studies, published reports and clinical experience that its product Yaz created an unreasonable risk of serious bodily injury and death to consumers, or should have known such information.
- 88. Defendants negligently and/or intentionally misrepresented or omitted this information in its product labeling, promotions and advertisements and instead labeled, promoted and advertised its product as safer and more effective than other types of oral contraceptives in order to avoid losses and sustain profits in its sales to consumers.

- 89. In supplying the false information, Defendants failed to exercise reasonable care or competence in obtaining or communicating information to Decedent and her healthcare providers
- 90. Decedent Melissa A. Fender and her healthcare providers reasonably relied to Melissa's detriment upon Defendants' misrepresentations and/or omissions in its labeling, advertisements, and promotions concerning the serious risks posed by the product. Decedent Melissa A. Fender reasonably relied upon Defendants' representations to her and/or her healthcare providers that Yaz was safer than other types of oral contraceptives for human consumption and/or use and that Defendants' labeling, advertisements and promotions fully described all known risks of the product.
- 91. As a direct and proximate result of Defendants' negligent and/or intentional misrepresentations or omissions, Melissa A. Fender suffered personal injuries, death, and economic and non-economic damages, including pain and suffering.
- 92. As a direct and proximate result of Melissa A. Fender's use of Yaz and resulting injuries, her mother, Plaintiff Jill Fender, has suffered damages and harm, including but not limited to, emotional distress and has incurred other medical expenses and other economic harm, as well as loss of consortium, services, society, companionship, love and comfort, and will continue to suffer such harm in the future.
- 93. Defendants' actions and omissions as identified in this Complaint demonstrate malicious actions, aggravated or egregious fraud, and/or intentional disregard of Decedent's rights so as to warrant the imposition of punitive damages.

#### SIXTH CAUSE OF ACTION

## **Intentional and Wanton Conduct and Request for Punitive Damages**

- 94. The Plaintiff hereby adopts and incorporates by reference all the above allegations.
- 95. At all material times, the Defendants knew or should have known that Yaz was inherently dangerous.
- 96. Despite their knowledge, the Defendants continued to aggressively market Yaz to consumers, including Plaintiff, without disclosing its dangerous side effects when there existed safer alternative products.
- 97. Despite Defendants' knowledge of Yaz's defective and unreasonably dangerous nature, Defendants continued to test, design, develop, manufacture, label, package, promote, market, sell and distribute, it so as to maximize sales and profits at the expense of the health and safety of the public, including the Plaintiff, in conscious disregard of the foreseeable harm caused by Yaz.
  - 98. The Defendants' conduct was intentional and/or wanton.
- 99. The Defendants' conduct as described above, including, but not limited to, their failure to adequately test their product, to provide adequate warnings, and their continued manufacture, sale, and marketing or their products when they knew or should have known of the serious health risks created, evidences a flagrant disregard of human life as to warrant the imposition of punitive damages as the acts or omissions were committed with knowing, conscious and deliberate disregard for the rights and safety of consumers, including Plaintiff.

## SEVENTH CAUSE OF ACTION

# **Breach of Express Warranty as to Bayer Defendants**

- 100. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs.
- 101. The Bayer Defendants expressly warranted that Yaz was a safe and effective prescription contraceptive.
- 102. The Yaz birth control patch manufactured and sold by Defendants did not conform to these express representations because it caused serious injury to consumers when taken in recommended dosages.
- 103. As a direct and proximate result of the Bayer Defendants' breach of warranty, Plaintiff has suffered harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

## EIGHTH CAUSE OF ACTION

#### **Breach of Implied Warranty as to Bayer Defendants**

- 104. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs.
- 105. At the time the Defendants designed, manufactured, marketed, sold, and distributed Yaz for use by Plaintiff, Defendants knew of the use for which Yaz was intended and impliedly warranted the product to be of merchantable quality and safe for such use.
- 106. Plaintiff reasonably relied upon the skill and judgment of the Defendants as to whether Yaz was of merchantable quality and safe for its intended use and upon the Defendants' implied warranty as to such matters.

- 107. Contrary to such implied warranty, Yaz was not of merchantable quality or safe for its intended use, because the product was reasonably dangerous as described above.
- 108. As a direct and proximate result of the Defendants' breach of warranty,
  Plaintiff has suffered harm, damages and economic loss and will continue to suffer such
  harm, damages and economic loss in the future.

## WHEREFORE, Plaintiff prays for relief as follows:

- 1. Compensatory and punitive damages in excess of the jurisdictional amount, including, but not limited to non-economic damages in excess of \$350,000.00;
- 2. Medical expenses and other economic damages in an amount to be determined at trial of this action;
  - 3. Attorneys' fees, expenses, and costs of this action;
  - 4. Punitive damages in excess of twice the compensatory damages award;
  - 5. Pain and suffering suffered by Decedent; and
  - 6. Such further relief as this Court deems necessary, just, and proper.

#### JURY DEMAND

Plaintiff hereby demands a trial by jury on all issues so triable.

Dated: July <u>27</u>, 2009

William R. Hughes, Jr. Robert M. Livingston

Ryan M. Sewell

STUART TINLEY LAW FIRM LLP 310 W. Kanesville Blvd., 2<sup>nd</sup> Floor

P.O. Box 398

Council Bluffs, IA 51502 Telephone: 712-322-4033

Fax: 712-322-6243

hughes.william@stuarttinley.com livingston.robert@stuarttinley.com sewell.ryan@stuarttinley.com

ATTORNEYS FOR PLAINTIFF

#### OF COUNSEL:

Roger C. Denton
Kristine K. Kraft
Elizabeth Wilkins
SCHLICHTER, BOGARD & DENTON
100 South 4<sup>th</sup> Street, Suite900
St. Louis, MO 63102
(314) 621-6115
(314) 621-7151 (facsimile)
rdenton@uselaws.com
kkraft@uselaws.com
bwilkins@uselaws.com

ATTORNEYS FOR PLAINTIFF